IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MDL No. 1:06-md-1789-JFK
BETTY J. DILLAHUNT, Plaintiff, v. MERCK & CO., INC. (hereinafter "Merck"), a New Jersey corporation, Defendant.	'07 CIV 11136 Case No _____ CIVIL COMPLAINT JURY TRIAL DEMANDED

COMPLAINT

Plaintiff, Betty J. Dillahunt, by and through her undersigned attorneys, sues Defendant Merck & Co., Inc. and alleges as follows:

1. Plaintiff is a resident of the State of Ohio, and Defendant, Merck, is incorporated and has its primary place of business in the State of New Jersey.

2. Plaintiff Betty J. Dillahunt was born August 18, 1921, and is a resident of Clark County, Ohio. After taking FOSAMAX for an extended period of time, Plaintiff was diagnosed with Osteonecrosis in 2006.

3. Defendant Merck is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's principal office is located at One Merck Drive, Whitehouse Station, New Jersey.

4. Defendant Merck was at all relevant times authorized to conduct business in the State of New York.

5. Defendant has regularly transacted business in the State of New York and continues to do so.

6. At all relevant times Defendant Merck, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis, osteopenia, and Paget's Disease.

7. Defendant Merck, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of New York and Ohio.

8. Defendants encouraged the use of this drug in improper customers, misrepresented the safety and effectiveness of this drug and concealed or understated its dangerous side effects in New York. These Defendants aggressively marketed this drug directly to the consuming public through the use of various marketing mediums, including, but not limited to, print and television advertisements in New York and Ohio.

9. Based on information and belief, Sales Representatives called on physicians on numerous occasions at which times they presented fraudulent information regarding the safety and efficacy of FOSAMAX and its harmful side effects, and/or fraudulently suppressed material information regarding the safety and efficacy of FOSAMAX and its harmful side effects, and/or placed FOSAMAX in the stream of commerce by providing Plaintiff's physician(s) samples of the drug FOSAMAX.

10. At all times material hereto Merck advertised, marketed, and/or promoted FOSAMAX to Plaintiff utilizing information known to fraudulently represent the safety

and efficacy of FOSAMAX and said Defendant failed to warn of the known dangers and adverse events associated with the use of the drug FOSAMAX.

11. At all times relevant hereto, the Defendant actually knew of the defective nature of its product as herein set forth, yet continued to design, manufacture, market, distribute and sell the product in New York and Ohio. Defendants' conduct exhibits an entire want of care as to the safety of this product and a conscious disregard of the foreseeable harm caused by this product in New York and Ohio.

12. Defendants derive substantial revenue from pharmaceutical products used or consumed in the State of New York and Ohio.

13. Defendants expected, or should have expected, that their business activities could or would have consequences within the State of New York and Ohio.

14. Defendants placed FOSAMAX into the stream of worldwide commerce and interstate commerce in the United States. They did so without adequate testing and with no warning that the drug carried with it a risk of causing osteonecrosis of the jaw.

15. Plaintiff needs continued medical monitoring to treat osteonecrosis of the jaw which has already manifested.

SUMMARY OF THE CASE

16. Merck, either directly, or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other uses.

17. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff, Betty J. Dillahunt, have suffered

and may continue to suffer severe and permanent personal injuries, including osteonecrosis of the jaw.

18. Merck concealed and continues to conceal its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff, Betty J. Dillahunt, other consumers, and the medical community.

19. Merck failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

20. As a result of Defendant's actions and inaction, Plaintiff Betty J. Dillahunt was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiff various injuries and damages. Plaintiff accordingly seeks compensatory damages, as well as other damages.

FACTUAL BACKGROUND

21. At all relevant times Merck was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

22. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Defendant Merck as FOSAMAX.

23. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class, such as Aredia and Zometa, are used

as chemotherapy and as adjunct chemotherapy but are not indicated for use in noncancerous conditions such as osteoporosis.

24. There are two classes of bisphosphonates: the N-containing (nitrogenous) and nonN-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphophonates include the following: pamidronate (Aredia); ibandronate (Bondronat); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate contains a nitrogen atom. The Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a nitrogen atom.

25. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).

26. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that Bisphosponates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and

maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.

27. Merck also knew or should have known that these factors combine to create a compromised vascular supply in the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).

28. Dentists are now being advised by dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

29. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and typically is not reversible.

30. Shortly after Merck began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Merck failed to further study the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendants proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.

31. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.

32. Since FOSAMAX was released, the FDA has received a significant number of reports of osteonecrosis of the jaw among users of FOSAMAX.

33. On August 25, 2004, the United States Food & Drug Administration ("FDA") posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.

34. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that osteonecrosis of the jaw was a class effect which specifically extended to the oral bisphosphonate, FOSAMAX.

35. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Defendant Merck to specifically warn about the risk of osteonecrosis of the jaw. Defendant Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.

36. Rather than warn patients, and despite knowledge by Defendants about increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendants continue to defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

37. FOSAMAX is one of Defendant Merck's top selling drugs, averaging more than $3 billion a year in sales.

38. Consumers, including Plaintiff Betty J. Dillahunt, who have used FOSAMAX for the treatment of osteoporosis, have several alternative safer products available to treat the conditions.

39. Defendants knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendants did not adequately and sufficiently warn consumers, including Plaintiff Betty J. Dillahunt, or the medical community, of such risks.

40. In an elaborate and sophisticated manner, Defendants aggressively marketed FOSAMAX directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payers, medical care organizations, and large institutional buyers (e.g., hospitals) to include FOSAMAX on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payers were compelled to add FOSAMAX to their formularies. Defendants' marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of FOSAMAX.

41. As a direct result, Plaintiff Betty J. Dillahunt was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff Betty J. Dillahunt requires and will in the future require on going medical care and treatment.

42. Plaintiff Betty J. Dillahunt has suffered and will continue to suffer from mental anguish with the knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff sustained from the use of FOSAMAX.

43. Plaintiff Betty J. Dillahunt was prescribed and began taking FOSAMAX in 2002.

44. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.

45. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe osteonecrosis of the jaw.

46. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and suffering and has sustained permanent injuries and emotional distress.

47. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.

48. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.

49. Merck, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Merck' fraudulent concealment.

50. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified

in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

COUNTS

COUNT I: NEGLIGENCE

51. Plaintiff restates the allegations set forth above as if fully rewritten herein.

52. The Defendant owed Plaintiff, Betty J. Dillahunt, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

53. The Defendant failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test FOSAMAX before releasing the drug to market;

b. Failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;

c. Failing to conduct sufficient post-market testing and surveillance of FOSAMAX;

d. Designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of

FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

e. Failing to exercise due care when advertising and promoting FOSAMAX; and

f. Negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

54. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff Betty J. Dillahunt sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

55. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendant and deter Defendant from similar conduct in the future.

COUNT II: STRICT LIABILITY

56. Plaintiff restates the allegations set forth above as if fully rewritten herein.

57. Merck manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff Betty J. Dillahunt.

58. Merck designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendant.

59. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.

60. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

61. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.

62. FOSAMAX was defective in design or formulation in that it posed a greater likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

63. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by

warnings adequate to alert consumers, including Plaintiff, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.

64. Although Defendant knew or should have known of the defective nature of FOSAMAX, Merck continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Merck acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

65. Plaintiff could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.

66. As a direct and proximate consequence of Defendant's conduct, Plaintiff Betty J. Dillahunt, sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

67. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling

Plaintiff to punitive damages so as to punish Defendant and deter Defendant from similar conduct in the future.

COUNT III: BREACH OF EXPRESS WARRANTY

68. Plaintiff restates the allegations set forth above as if fully rewritten herein.

69. Defendant expressly represented to Plaintiff Betty J. Dillahunt and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

70. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries.

71. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

72. Plaintiff Betty J. Dillahunt, other consumers, and the medical community relied upon Defendant's express warranties.

73. As a direct and proximate result of Defendant's actions, Plaintiff Betty J. Dillahunt sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished

quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

84. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter Defendant from similar conduct in the future.

COUNT IV: BREACH OF IMPLIED WARRANTY

85. Plaintiff restates the allegations set forth above as if fully rewritten herein.

86. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

87. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

88. Merck was aware that consumers, including Plaintiff Betty J. Dillahunt, would use FOSAMAX for treatment of osteoporosis and for other purposes.

89. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.

90. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.

91. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

92. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.

91. As a direct and proximate result of Defendants' action, Plaintiff Betty J. Dillahunt sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

92. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling

Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT V: FRAUDULENT MISREPRESENTATION

93. Plaintiff restates the allegations set forth above as if fully rewritten herein.

94. Merck made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of pain and inflammation; and

b. Defendant represented that FOSAMAX was safer than other alternative medications.

95. Defendant knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

96. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

97. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

98. Plaintiff's doctors and others relied upon the representations.

99. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

100. As a direct and proximate result, Plaintiff Betty J. Dillahunt sustained osteonecrosis of the jaw. In addition, Plaintiff required and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

101. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

COUNT VI: FRAUDULENT CONCEALMENT

104. Plaintiff restates the allegations set forth above as if fully rewritten herein.

105. Merck's fraudulently concealed information with respect to FOSAMAX in the following particulars:

a. Merck represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and

b. Merck represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.

106. Merck had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.

107. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant to be false.

108. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.

109. Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.

110. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentation, Plaintiff Betty J. Dillahunt suffered osteonecrosis of the jaw and was caused to suffer severe and permanent injuries, including pain and mental and physical anguish and suffering, including a diminished capacity for the enjoyment of life, aggravation of preexisting conditions and activation of latent conditions, and a fear of developing other harmful conditions or problems as a result of the injury. Plaintiff has incurred expense for medical care and treatment due to the injuries caused by FOSAMAX and will do so in the future.

111. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter Defendant from similar conduct in the future.

COUNT VII: PUNITIVE DAMAGES

112. Plaintiff restates the allegations set forth above as if fully rewritten herein.

113. Merck has repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations relating to public hazards about which the public should be warned.

114. For instance, in March 2000, Merck completed a study called VIGOR (VIOXX Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, VIOXX. The VIGOR study showed that VIOXX patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug. The study was published in the New England Journal of Medicine.

115. In September 2001, the FDA warned Merck to stop misleading doctors about VIOXX's effect on the cardiovascular system. Defendant Merck was admonished to stop minimizing the risks of the drug in its marketing. Despite that, Defendant Merck refused to adequately warn physicians and patients about the risk of heart attacks and VIOXX.

116. On August 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that VIOXX users were more likely to suffer a heart attack or sudden cardiac death than those taking older non-steroidal drugs. The FDA representative concluded that VIOXX was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

117. On August 26, 2004, Merck released a press statement which refuted the FDA analysis and restated Merck's support for the cardiovascular safety of VIOXX.

118. On September 30, 2004, Merck recalled VIOXX from the market, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway to evaluate the use of VIOXX for recurrent colon polyps. The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.

119. At that same time, Merck was aware that the FDA, as of August 24, 2004, was advising Merck to warn about the risk of osteonecrosis of the jaw for its FOSAMAX patients. Because Merck knew that its blockbuster drug VIOXX was about to be pulled from the market, placing more importance on the $3 billion annual sales of FOSAMAX, Merck deliberately chose to not amend its packaging of FOSAMAX to include the risk of osteonecrosis of the jaw, fearing that such a warning would result in reduced revenues for its second largest income producer, FOSAMAX.

120. Merck's acts were willful and malicious in that Merck's conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs. Defendant's unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Merck in an amount appropriate to punish Merck, and deter similar conduct in the future.

WHEREFORE, Plaintiff prays for judgment against Defendants, jointly and/or severally, as follows:

1. For general damages in an amount to be proven at the time of trial;

2. For special damages in an amount to be proven at the time of trial;

3. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;

4. For pre-judgment and post-judgment interest on the above general and special damages;

5. For costs of this suit and attorneys' fees; and

6. All other relief to which Plaintiff may be entitled.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

DATED: December 7, 2007

E. FRANK WOODSON
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